



## Post Authorisation Assessments

### Baytril 2.5% Oral Solution

Vm 00879/4117

•	15 September 2023	User safety warnings updated regarding potential allergic reactions to fluoroquinolones.
•	06 May 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	08 October 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	12 June 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
•	05 June 2018	Deletion of a supplier of packaging components or devices.
•	05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD
•	09 August 2016	Change to more restrictive storage conditions of the active substance.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	12 April 2011	Change in shape/dimensions of the immediate packaging
•	16 February 2011	Change of distributor
•	09 March 2009	Change in name of manufacturer of the active substance
•	08 February 2008	Renewal
•	12 September 2007	Corrections to the SPC and Product Literature
•	21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 January 2005	Change of manufacturer of the active substance
•	24 November 2004	Harmonisation of the SPC
•	08 October 2004	Change to specification of the active substance
•	23 September 2004	Change to the batch size of the active substance

•	11 March 2004	Renewal
•	30 January 2004	Change to MAH address
•	13 June 2001	Change to specification of the finished product
•	21 June 2000	Renewal
•	29 March 2000	Change in specification of the active substance Change of manufacturing process of the active substance
•	04 June 1998	Update of licence particulars
•	29 January 1998	Use in additional non-food species (Exotic animals and avian species)
•	05 March 1997	Renewal